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EXAMINER

MEAH, MOHAMMAD Y

ART UNIT

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1652

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

With supplemental amendment, filed 5/24/2010, in response the office action, mailed on 1/22/2010, the applicants amended claims 1, 4-5 and cancelled claims 6-7. Claim 8-15 remain withdrawn. Applicants' after final amendment filed on 5/24/2010 has been entered because it does not raise any new issue, or new matter.

Applicants' arguments filed on 5/24/2010, in response to a previous office action mailed on 1/22/2010, have been fully considered but they are found unpersuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Objection

Claims 4-5 are objected for comprising non-elected subject matter (SEQ ID NO: 1 in claim 4 and SEQ ID NOs: 3, 5-8 in claim 5). Appropriate correction is required.

Claim Rejection 35 U.S.C 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention as explained in prior office action and stated again below:

Claims 1-3 are directed to a therapeutic composition comprising the active portion of any lysyl oxidase pro-peptide lacking enzymatic activity having any structure (claims 1-3). The specification teaches the structure of only a few representative species of such lysyl oxidase pro-peptides and fragments thereof lacking enzymatic activity, i.e., the human polypeptides of SEQ ID NOs: 1, 3 and 6; the mouse polypeptides of SEQ ID NOs: 2, 4 and 7, and the rat peptides of SEQ ID NOs: 5 and 8. SEQ ID NOs: 1 and 2 are full length lysyl oxidase pro-peptides and SEQ ID NO: 3-8 are fragments of human, rat and mouse lysyl oxidase pro-peptides comprising 35-38 amino acids. The specification fails to describe any other representative species by any identifying characteristics or properties other than the biological activity lacking enzymatic activity. Prior art teach a small number of species having lysyl oxidase activity (EC 1.4.3.13 in EXPASY search results attached). In view of the fact that a structural/functional correlation that would allow one of skill in the art to envision the structure of additional lysyl oxidases is unknown, and the number of known species is small, one cannot reasonably conclude that the structural features required in any protein having lysyl oxidase activity are adequately described by the specification and/or the art.

Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full,

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clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

In the instant case the scope of the instant claims encompass a genus of polypeptides which are lysyl oxidase pro-peptides lacking enzymatic activity having any structure. The claimed therapeutic composition comprises a polypeptide **having any structure**. The prior art, as evidenced by WO/0185157, teaches a few lysyl oxidases and the specification teaches (page 3) three lysyl oxidase pro-peptides and fragments thereof (SEQ ID NOs: 1-8). However, the specification fails to describe any other representative species by sufficient identifying characteristics or properties to show that applicant was in possession of the claimed genus.

Claims 1-3 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for therapeutic composition comprising any of the peptides of SEQ ID NOs: 1-8, and a method of identifying the minimum portion of the lysyl oxidase pro-peptides of SEQ ID NO: 1 or 2 which has cell growth inhibiting activity, , does not reasonably provide enablement for (A) any therapeutic composition comprising (1) any lysyl oxidase pro-peptide having any structural. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The breadth of the claims: Claim 1-3 are broadly directed to include (A) any therapeutic composition comprising any lysyl oxidase pro-peptide having any structure.

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The state of the prior art; the relative skill of those in the art; and the predictability or unpredictability of the art:

Neither the specification nor the state of the art at the time of the invention provided the necessary guidance for correctly identifying based solely on structural features which proteins have lysyl oxidase activity so that their pro-peptide can be identified and which would have cell growth inhibiting activity. At the time of the invention, there was a high level of unpredictability associated with altering a polypeptide sequence with an expectation that the polypeptide will maintain the same desired biological activity. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g., multiple substitutions, deletions, additions, and combinations thereof.

The amount of direction provided by the inventor; and the existence of working examples: The specification fails to provide any specific guidance for obtaining any lysyl oxidase or its corresponding pro-peptide such that they would display cell growth inhibiting activity.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure: While methods of isolating and/or generating variants of a polypeptide were known in the art at the time of the invention and the specification provides general teachings for searching and screening for the claimed invention, it was not routine in the art to screen by a trial and error process for all polypeptides having lysyl oxidase activity and their corresponding pro-peptides, nor was it routine in the art to make an infinite number of structural variants and test them for a desired activity.

Claim Rejection - 35 U.S.C 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 remain rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (WO/0185157, November 15, 2001). Li et al teach a therapeutic composition comprising a lysyl oxidase polypeptide of human (page 5) without catalytic activity for the treatment of cancer/tumors (page 10 lines 25-33, and page 13, lines 25-28). The lysyl oxidase of Li et al. having no catalytic activity would include the pro form of the enzyme (pro-peptide linked to the mature enzyme). Since claims 1-3 are directed to a composition that has a polypeptide that comprises the pro-peptide, the pro form of the lysyl oxidase of Li et al. having no catalytic activity is a species of the genus of polypeptides comprising the pro-peptide recited in claims 1-3. Limitations regarding inhibition of cell growth in agar or in inhibition of tumor formation are inherent to the pro form of the lysyl oxidase of Li et al. as evidenced by the specification which teaches that the lysyl oxidase pro-peptide has those activities. As such, the teachings of Li et al. anticipate the instant claims as written.

Allowable Subject Matter

Claims 1-3 is rejected and claims 4-5 are objected for depending on rejected claims. No claim is allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Mohammad Younus Meah
Examiner, Art Unit 1652

/Delia M. Ramirez/
Primary Examiner, Art Unit 1652